

**A Guide to Health and Safety Requirements for Exports
to Central and Eastern Europe**

August 2001

Albania

For products requiring certification (ie: medicines), Albania accepts all certification from valid U.S. agencies such as the U.S. Food & Drug Administration.

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Bulgaria

Upon arrival, products for human consumption should be analyzed in approved local laboratories in cooperation with local authorities. The Bulgarian Agency for Standardization and Metrology strictly enforces Bulgarian quality standards, which do not always coincide with generally accepted international standards. Foreign certificates may or may not be considered adequate. After approval is issued, the commodities may be sold on the local market.

The Agency for Standardization and Metrology is the designated authority for developing national standards. The Agency for Standardization and Metrology reports to the Council of Ministers. In certain areas, product and sector-specific standards are issued by other appointed ministries or agencies.

The Agency for Standardization and Metrology is the competent authority for testing and certification of all products except pharmaceuticals, food and telecommunications equipment. The Agency issues approvals attesting to electrical safety and functional characteristics. The Department for Certification and Management Quality Control, within the Agency, handles all testing and certification. In addition to the application, the Department requires a Bulgarian translation as well as certificate(s) of approval from the corresponding home testing authority and a certificate identifying the testing protocol. The fee levied for the testing and certification process is BGN 50-70 per application. The entire testing and certification process requires at least one month. Certificates are valid for two years.

The Agency for Standardization and Metrology shares responsibilities for food products with the Ministries of Agriculture and Health. The responsible authority for pharmaceuticals is the National Institute for Pharmaceutical Products in the Ministry of Health, which establishes standards and performs testing and certification and is also responsible for drug registration. Approval for any equipment interconnected to

Bulgaria's telecommunications network must be obtained from the State Telecommunications Commission.

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State Telecommunications Commission
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Tel: (359)(2) 949-2335
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Ministry of Agriculture, Forestry and Agrarian Reform

55, Khristo Botev Boulevard
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Tel: (359)(2) 980-7873
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General Customs Directorate
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1000 Sofia
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Croatia

Generally, standards is not a concern. However, certain products do have mandatory standards that require certification by Croatian state agencies and ministries. Accreditation of laboratories and certification bodies will be done according to the EN 45000 (European standards). A complete list of standards can be obtained from the Croatian Office for Standards and Measures.

Most equipment is subject to safety requirements that are not listed as standards but are prescribed in the Law on Safety at Work. Information on these requirements can be obtained from the Ministry of Labor and Social Welfare

Cars, furniture, cement, textiles and other appliances which may be dangerous for the consumer, are subject to quality control by inspection officials (employees of the Ministry of Economy) at Customs. Other products may also have to pass sanitary, phytopathologic or veterinary control. Information on sanitary requirements can be obtained from the Ministry of Health, and information of phytopathologic and veterinary requirements from the Ministry of Agriculture and Forestry.

Pre-customs quality inspections are now required for products made from fish or other sea foods, milk and milk products, coffee, coffee products and substitutes, egg products, fruit, vegetables, and mushroom products, ice cream and other frozen desserts, mustard, spices, extracts, and cooking salts and brine salt. To clear inspection with any of these, importers must submit a request 24 hours in advance of reaching customs. Invoices and product specifications must be included. Importers must also delegate a representative to attend the inspection and provide product samples. To meet the requirement of having a designated representative on sight at inspection, exporters often use a local freight forwarder. A list of local freight forwarders can be obtained from U.S. Commercial Service Zagreb.

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Ministry of Agriculture and Forestry
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Czech Republic

The Czech Republic has begun accession negotiations with the European Union and as such is in the process of harmonizing its standards based on European and international norms. For up-to-date information on standards in Czech Republic, contact the Central and Eastern Europe Business Information Center (CEEbic).

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Estonia

Live animals and birds, live fish and other water organisms, products of animal, poultry and fish breeding, feed and feed additions and veterinary medicaments, diagnostics and vaccines are subject to veterinary control. The Border Inspectorate of National Veterinary Control carries out border inspections.

Goods subject to veterinary control may be conveyed across the border through the following border control offices and stations: Tallinn City port, Muuga port, Tallinn Airport, all the border custom control stations on the Narva road and railway, Ikla, Koidula, Luhamaa, border control stations in Murati, Pärnu port, Pärnu airport, Tartu goods station, Tartu Airport, Valga road, Valga railway, ports in Hiiumaa, Kõrvald airport, ports in Saaremaa, Kuressaare airport, Dirham port, SE Estonian Post.

When the goods arrive to the border control office, the customs official directs the consignor, the receiver of the goods, or their authorized person to the veterinarian of the local or of the nearest Border Inspectorate. On the basis of the results of the control carried out by the inspector, goods are either allowed or prohibited from crossing the border. The customs official will allow the goods to be conveyed across the Estonian

border only if there is a note of the Border Inspectorate about the veterinary control on all the copies of accompanying documents and customs documents.

When crossing the Estonian border, the goods must have the original of the veterinary certificate issued by the national veterinary organization of the country of departure.

Veterinary medicaments, diagnostics and vaccines are allowed to be imported to Estonia only by the firms having the national licence for wholesale of medicaments issued by the National Veterinary Board.

Foodstuffs meant for personal use during the journey are not subject to veterinary control with the exception of raw flesh.

For applications and requests concerning the issues of veterinary control contact: Border Inspectorate of Veterinary Inspection or the Office of State Veterinary and Food Inspection.

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FYR Macedonia

The Law on the Protection and Improvement of the Environment and Nature (official Gazette No. 69/1996) regulates safety standards for import/export purposes.

A number of products are subject to quality control by market inspection officials at customs offices. These officials are employed by the Ministry of Economy to ensure that imported goods are in compliance with the domestic standards. The products subject to quality control include most agricultural products, cars, electrical appliances or products in which improper quality may pose a health risk to consumers. When applicable, products also must pass sanitary, phytopathologic or veterinary control. (Additional information on sanitary requirements can be obtained from the Ministry of Health, and phytopathologic and veterinary requirements can be obtained from the Ministry of Agriculture, Forestry and Water Resource Management.)

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Hungary

Hungary has begun accession negotiations with the European Union and as such is in the process of harmonizing its standards based on European and international norms. For up-to-date information on standards in Czech Republic, contact the Central and Eastern Europe Business Information Center (CEEbic) or contact the appropriate Hungarian agency directly.

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www.mecei.hu

For medical devices:

National Institute for Medical Engineering (ORKI)
Diosarok utca 3
1125 Budapest, Hungary
Tel: (36-1) 356- 1522
Fax: (36-1) 375-7253
www.orki.hu

For pharmaceuticals:

National Institute of Pharmacy (OGYI)
Zrinyi utca 3
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Tel: (36-1) 317-1462 or 317-1488
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For gas appliances, boilers, and appliances operating in an environment with danger of explosion:

Technical Safety Testing and Certifying Institute (MBVTI)
Logodi u. 38-40
1012 Budapest, Hungary
Mailing address:
P.O. Box 39
1255 Budapest, Hungary
Tel: (36-1) 212-3032
Fax: (36-1) 375-4130

E-mail: mbvti@mail.mata.v.hu

Kosovo ('FRY')

The Kosovo Drug Regulatory Authority has issued the following quality and safety requirements for pharmaceutical products (UNMIK regulation no. 52): (a) Every pharmaceutical product which is imported must be accompanied by a certificate ensuring product quality and safety (such as, a certificate according to the World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce); (b) Documents justifying the use of the product in Kosovo; (c) Certificate of Analysis showing test results of a pharmaceutical product may be required in some circumstances; (d) The shelf life of imported pharmaceutical products must be at least one year from the delivery into Kosovo.

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Latvia

Meat imports are subject to inspections from the State Veterinary Department which provides border inspection controls for bovine spongiform encephalopathy, classical swine fever, salmonella, etc.

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Lithuania

For meat imports, the state veterinary department provides border inspection controls for bovine spongiform, encephalopathy, classical swine fever, salmonella, etc. Imported food products are required to have conformity certificate to guarantee quality and wholesomeness of food products. A producer's declaration or a food conformity certificate is required for food imports, cosmetics, and toys.

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Poland

Poland has a very complex safety certification regime. U.S. exporters are strongly urged to contact the Central and Eastern Europe Business Information Center (CEEIBIC) for specific guidance.

"B" Safety Certificates

Beginning January 1, 1999, about 1,400 different products will probably require a "B" mark certificate (for "bezpieczenstwo," "safety" in Polish) to clear customs (domestically produced products also require certification). This requirement was expected to be

introduced beginning in 1995, 1996, 1997, and then 1998, but was postponed for each of the last four years. The list of goods that require the certification, originally published in 1994, has been modified every year since. Testing for the "B" mark is performed by the Polish Certificate and Testing Center (PCBC) or one of the fifteen specialized institutes authorized and supervised by the PCBC. Firms selling goods without the B mark or manufactured inconsistently with the mark are obligated to pay fines amounting to 100% of the value of the goods sold.

Other Polish Standards: PN and BN

Polish standards describing a wide range of products have been developed by a central institution, the Polish Standards Committee (PKN), over the years. These standards have a PN prefix. The Government of Poland, through its ministries, decides which of them are obligatory. Also ministerial regulations clarify what standards a particular product must meet to be admitted into Poland. Standards developed by industry branches or industrial associations, were marked BN. They defined products of a particular industry branch and initially they were only valid for specialists in the particular branch of industry. The prefixes PN and BN still exist. Descriptions of these standards are available at the central library of PKN.

Introducing Building Products: Technical Approvals

In the case of many building products new to Poland no standards exist. However, when introduced into the Polish market the products need to have documentation certifying that they are in conformity with existing standards. They must therefore receive technical approval, a document issued by designated research and development institutes.

The central institution performing these tests for a vast majority of building products and materials is the Institute for Building Technology (ITB) in Warsaw. It deals with products like siding, roof shingles, bricks, etc.

Some building products, after receiving technical approval, or when PN or BN standards can be applied in their case, may still require the "B" Certificate. They must then go through the certification process designed by PCBC. The standards for the "B" Certificate are available only at the PCBC. This certification process takes time. However, the official regulations specify that this process should not exceed 3 months.

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Romania

Romanian standards of quality and safety are under the jurisdiction of the Romanian Institute for Standardization. Generally, they match ISO and Western European Standards. Romania adopted, for instance, international quality control standards such as

ISO 8402, 9000-9004 and 9004-2 and incorporated them in its national standardization system.

Although the ISO standards are not compulsory by law for individual companies, the buyers increasingly impose on the suppliers to prove the quality of their products and services by the certification of the quality control system they practice. Generally speaking, American quality standards requirements are superior to local ones.

On November 28, 1996, officials from the Romanian Standards Institute and the Ministry of Commerce informed U.S. officials of new standards requirements for certain categories of imports. These new standards are identical with European Union standards criteria and consistent with the World Trade Organization and European Union rules.

Certification of Conformity: Construction materials, gas-driven machines, high-voltage electrical equipment and electrical appliances which are potentially explosive, protection equipment, pressurized containers, toys for children under age 14, food products and processed foods must be accompanied by a Certification of Conformity. The Certification is generally issued in

the country of origin, verifying the product meets standards covering environment, public safety, and public health concerns. However, Romanian officials have not yet contacted the American Standards Coordinating Organization which will help compile a list of U.S. organizations that will issue Certifications of Conformity. After a list is completed, U.S. exporters will be

required to provide a Certification of Conformity from one of the qualified U.S.-based organizations. CEEBIC will publicize this list when it is completed. In the interim, U.S. Department of Commerce officials have encouraged Romanian officials to accept documents similar to the examples below for products exported to Romania.

Exporters need to send an original, not faxed, declaration of conformity for Romanian customs. The declaration should be on company letterhead, dated, and signed by a responsible company official. The recommended format for a certification of conformity is:

We (supplier's name and address) declare under our sole responsibility that the product (name, type or model, batch or serial number, sources and numbers of items available) to which this declaration relates is in conformity with the following standards or other normative documents (title or number and date of issue of standards or normative documents) and, if applicable, following the provisions of (directive).

Romanian ministry officials also provided a copy of a recent declaration made by an Austrian firm which stated:

We hereby confirm that (product name) is non-toxic and non-dangerous to the environment, public health, and public safety if it is used according to the manufacturer's

instructions. We also confirm that the supplied goods have been inspected and tested in accordance with the conditions and requirements of the manufacturer.

Since November 1996, U.S. companies exporting the goods listed above have successfully passed through Romanian Customs by drafting this document, indicating that their products are CE, NOM or UL certified (or need no certification) and including test results obtained by the manufacturer with the Certification of Conformity.

Phytosanitary Certificate: Certain plants and plants products, including oak logs and lumber, potatoes, and corn require a phytosanitary certificate.

APHIS inspects meat and poultry to assure that they comply with U.S. standards and with requirements of the country of destination. Although information on documents required for the exportation of agricultural products (including food items), plants, and animals is available from the U.S. Department of Agriculture, U.S. exporters also should obtain information directly from Romanian importer prior to shipping the goods. Information also can be obtain from the appropriate ministry of the Romanian government.

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Slovak Republic

The Slovak Office of Standards, Metrology and Testing (OSMT or in Slovak, UNMS) is the Slovak government agency which coordinates and implements the standards certification. National Testing Centers (NTC) do the testing of products and sends the approval to the OSMT which in turn issues the certificates. There are several testing centers each of which specializes in different categories of products.

The Slovak authorities' requirements for standards certification changed on September 20, 1997. The Slovak customs offices now requires importers to submit certificates attesting to the quality and safety of approximately nine percent of imported products prior to physical entry of the goods into the country. Each certificate must be approved by the Slovak Office of Standards, Metrology and Testing and must bear the Sk 1000 (about \$30) stamp attesting the approval of OSMT. The products consist mainly of foodstuffs, kitchen devices, medicines, electrical equipment, engineering products, agricultural machinery, plastics, paints, polishes, cosmetics, and sporting goods.

The certification process begins when the importer fills out an application form supplied by a Slovak National Testing Center. The application form becomes the actual certification document once it has been approved by the appropriate NTC and OSMT and has the Sk 1000 stamp. Substantial documentation may need to be supplied to the NTC to prove compliance with applicable products standards.

Certification of a product is carried out by a National Testing Center only if the product falls within the center's competence. The applicant is required to state the technical standards, technical documents or legal regulations according to which he or she wants the product to be certified. If certification is to be carried out according to foreign technical standards, technical documents or legal regulations, the applicant must submit copies to the NTC together with the application for certification.

If the name of the imported product and the names of the producer and importer are the same as listed on the certificate for every shipment, the same certification may continued to be used for multiple shipments.

Conversely, certified products must be re-certified if they are supplied by a new producer or brought in by a different importer. The new producer or importer is obliged to notify the appropriate NTC and begin a new certification process within 30 days following the day of having taken over the production or import of the product. The new producer or importer can keep certified products on the market during the re-certification procedure if the conditions stated in the original certificate are fulfilled. Some certificates may be of limited duration, and producers or importers must accordingly apply for re-certification in timely fashion if the product is to remain on the Slovak market.

Products that have been certified in the Czech Republic under international agreements between the Czech and Slovak Republics may be imported into Slovakia. Prior to the first delivery to the Slovak Republic, the importer should notify the appropriate National Testing Center, or the OSMT in cases in which the appropriate NTC cannot be determined, that certification has already been obtained in the Czech Republic.

One of the several National Testing Centers, the Electrotechnical Research and Design Institute (in Slovak, EVPU), will accept CB and/or CCA certificates automatically without requiring further testing in Slovakia. CB certificates are certification body documents issued by a U.S. testing center. CCA certificates are CENELEC Certification Agreement documents issued by testing centers located in the European Union. EVPU verifies if technical parameters and norms of these certificates meet Slovak technical, environmental and other norms. The EVPU then sends its approval usually within 15 days to the OSMT which then issues the certificate.

U.S. companies may obtain the complete list of products which require obligatory certification as well as contact addresses of National Testing Centers from the Slovak Office of Standards, Metrology and Testing.

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Mr. Andrej Svatik, Director of International Relations
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Fax: (421-7) 394-728

Slovenia

Products being imported into Slovenia may have to conform to the regulations of the Slovenian Institute of Standardization (SIST). The conformity of a product, production process, or service may be certified by a conformity statement, conformity certificate or conformity mark. The SIST may also accept European Union or other foreign standards. Certificates issued abroad are valid in Slovenia if the issuing authority and the local issuing institution have signed an agreement on the mutual recognition of certificates.

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Miscellaneous

CE Mark

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Food and Drug Administration (FDA) Certificates of Free Sale

Biologics
(301) 827-6201
Cosmetics and Colors
(202) 205-4530
Foods and Beverages
(202) 205-4618
Foods-Seafood
(202) 418-3148
Foods-Special Nutritionals
(202) 205-5106
Human Drugs
(301) 594-3150

Medical Devices and Radiation Products
(301) 827-4555
Veterinary Foods and Drugs
(301) 594-1785

Information in this document is subject to change without notice. U.S. companies should contact the Central and Eastern Europe Business Information Center (CEEBC) for the most up-to-date information.